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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/051,307 | 01/22/2002 | Ziyu Dai | 059440-0141 | 4790 |

21567 7590 03/30/2005
WELLS ST. JOHN P.S.
601 W. FIRST AVENUE, SUITE 1300
SPOKANE, WA 99201

EXAMINER

KOROMA, BARBA M

ART UNIT PAPER NUMBER

1638

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------|--------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/051,307 | DAI ET AL. | |
| | Examiner | Art Unit | |
| | Barba M. Koroma | 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,7,9,11,12,16 and 18-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6,18,20,21,22,23 is/are allowed.
- 6) ☒ Claim(s) 1,2,5,7,9,11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Objections to Specification

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Objections to Figure 1 of the specification is maintained because the response only partly addresses the objection as it pertains to 'shaded area 100'. However the amendment does not address an underlined sequence, "ATGC," that appears in Figure 1.
3. Other objections to the specification have been corrected and or amended in accordance with previous objections and have therefore been withdrawn accordingly.

Objections to Claim

4. Objections to claims 5 and 16 have been corrected and objections hereby withdrawn.

Claim Rejections

35 USC 112 Second Paragraph

5. Rejections directed at claims 1 and 11 have been corrected and the rejection is withdrawn accordingly.

6. Claim Rejection

35 USC 112 Second paragraph

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what the recombinant polynucleotide of claim 19 comprises that is not encompassed by claim 18. The metes and bounds of the claims are unclear.

35 USC 112 First Paragraph

Written Description

7. Claims 1, 2, 5, 7, 9, 11, 12, remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office Action mailed 9/24/04. Applicants traverse the rejection in the paper submitted October 28, 2003. Applicant's arguments were fully considered but not found persuasive.

Applicant argues that identification of each and every location within a promoter sequence necessary for activity is not required (response, page 21, 2nd full paragraph). However, it is these

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locations that are necessary to correlate the structure of the promoter with its activity. These undescribed essential regions would be present in every species of the claimed genus.

This rejection is traversed by Applicant because “one skilled in the art could produce isolated polynucleotide having 70% identity to SEQ ID No. 1 and or fragments of SEQ ID No. 1, 2 or 3 which comprise promoter activity.” Applicant maintained that it would be clear to one skilled in the art that the inventor had possession of the claimed polynucleotide sequences at the time the application was filed (response, page 21, 2nd full paragraph).

Examiner maintains that Applicant’s specification does not provide any description of the structure of any sequences that are fragments or are minimally 70% of the full-length of cDNA sequences of SEQ ID Nos. 1-3, that retain pin1 promoter activity. A method of producing an isolated polynucleotide does not describe the polynucleotide itself. See Fiers vs. Revel, 25 USPQ 2d (CAFC 1993) at 1606, which states that “[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself”.

The rejection is maintained.

35 USC 112 First Paragraph

Enablement

8. Claims 1, 2, 5, 7, 9, 11, 12, ^{remain} rejected under 35

U.S.C. 112, first paragraph, because the specification, while being enabling for the promoter

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sequence of SEQ ID Nos. 1, 2 and 3, does not reasonably provide enablement for isolated polynucleotides having at least 70% sequence identity to SEQ ID No. 1 or fragments of SEQ ID Nos. 1-3, that retain *pin1* promoter activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims. for the reasons of record stated in the Office Action mailed 9/24/04. Applicants traverse the rejection in the paper submitted October 28, 2003. Applicant's arguments were fully considered but not found persuasive.

However, the specification does not provide any guidance regarding the domains of SEQ ID No. 1-3 that are essential for promoter activity, and which one skilled in the art must include in each of the polynucleotides encompassed by the claims. The claimed sequences can differ from SEQ ID No. 1 in as many as 479 nucleotides. Any of 1-479 nucleotides of the 1595 nucleotide sequences may differ. In the absence of further guidance, undue experimentation would be required by one skilled in the art to determine what regions will sustain a change in sequence without affecting promoter activity.

Applicant also traverses on the basis that examples of issued patents exist with 'percent identity or fragment of a promoter sequence' claim language (response paragraph bridging pages 21-22). In response to that argument, Examiner maintains every patent has a unique set of circumstances, fact patterns. Therefore the cited patents may be irrelevant to this case.

This rejection is traversed by Applicant because “functional elements of the promoters can be identified using methods known to those skilled in the art and subclones corresponding to functional fragments can be identified by operable linkage to screenable markers and testing utilizing transformed cells. Accordingly, one skilled in the art could identify and/or produce the polynucleotide molecules recited in the claims without undue experimentation (page 21, first full paragraph).

Other cells from bacterial, fungal, and animal origins are encompassed by the claims but are not described in the specification. Using a plant promoter in non-plant host cells may present highly unpredictable outcomes for successful integration and activity.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Conclusion

10. Claims 16, 18, 20, 22 and 23 are allowable in this application. Claims 1, 2, 5, 7, 9, 11, 12, 19 and 21 are rejected.

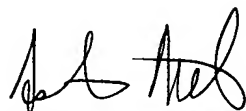
Contact Information

11. Any inquiry concerning this or earlier communications from the Examiner should be directed to Barba M. Koroma, whose telephone number is 571-272-0899. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 571 273 8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Bmk

March 21, 2005


ASHWIN D. MEHTA, PH.D.
PRIMARY EXAMINER